

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

006270

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

APR - 8 1987

MEMORANDUM

SUBJECT: EPA File Symbol 7969-TT  
Doble Herbicide

FROM: Deloris F. Graham *DFG 4/13/87*  
Technical Support Section  
Fungicide-Herbicide Branch  
Registration Division (TS-767C)

TO: Robert J. Taylor, PM 25  
Fungicide-Herbicide Branch  
Registration Division (TS-767C)

APPLICANT: BASF Corporation Chemicals Division  
100 Cherry Hill Road  
Parsippany, NJ 07054

ACTIVE INGREDIENTS:  
Sodium salt of bentazon . . . . . 33.0%  
Sodium salt of acifluorfen . . . . . 7.1%  
INERT INGREDIENTS: . . . . . 59.9%

BACKGROUND:

Submitted Acute Oral, Acute Dermal, Eye Irritation, and Dermal Irritation Studies to support conditional registration of this product. Justification for not conducting Acute Inhalation and Dermal Sensitization Studies was submitted. Studies conducted by BASF. Studies under MRID Nos. 400313-02, 400313-03, 400313-04, and 400313-05. Method of support not indicated.

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RECOMMENDATIONS:

1. FHB/TSS finds the studies submitted acceptable to support conditional registration of this product (7969-TT).
2. Based on information submitted by applicant, the active ingredient Bentazon (EPA Registration No. 7969-42) is a skin sensitizer; therefore, they wish to label this product as a skin sensitizer and not conduct a separate sensitization study, which is acceptable to the Agency.
3. *The Acute Inhalation Study submitted under EPA Registration Number: 7969-76 as cited by this applicant is acceptable to support conditional registration of this product (EPA Reg. No. 7969-TT)*
4. ~~5.~~ *The appropriate signal word is DANGER.*

LABEL:

No additional labeling comments required at this time.

REVIEW:

- (1) Acute Oral Toxicity Study: BASF Aktiengesellschaft Lab; Project ID 10A125/85; April 28, 1985; EPA MRID No. 400313-02.

PROCEDURE:

Three groups consisting of five male and five female rats each were dosed with one of the following doses: 1210, 1780, or 2610 mg/kg. Observations made for 14 days postdosing. Necropsy performed on all animals.

RESULTS:

At 1780 mg/kg, 4/5 M and 5/5 F died; at 2610 mg/kg, 5/5 M and 5/5 F died. Toxicity signs reported included dyspnea, apathy, staggering, paresis, twitching, and poor general state. Necropsy report revealed general congestive hyperemia and effects in livers of animals that died during study. No abnormalities reported at necropsy of sacrificed animals. LD<sub>50</sub> for males and females individually and combined reported to be greater than 1210 mg/kg but less than 1780 mg/kg.

006270

3

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

- (2) Acute Dermal Toxicity Study: BASF Aktiengesellschaft; Project ID 11A125/85; May 28, 1985; EPA MRID No. 400313-03.

PROCEDURE:

Five male and five female rats each received 2000 mg/kg of the test material at intact skin sites under semioclusive wrap for 24-hour exposure. Observations made for 14 days posttreatment. Necropsy performed on all animals.

RESULTS:

No mortalities or abnormalities at necropsy reported. Erythema reported in one male and one female rabbit. LD<sub>50</sub> reported to be greater than 2000 mg/kg.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

- (3) Eye Irritation Study: BASF Aktiengesellschaft; Project ID 13H125/85; April 23, 1985; EPA MRID No. 400313-04.

PROCEDURE:

Six rabbits received 0.1 ml of the test material in one eye each. Observations made for 8 days posttreatment.

RESULTS:

At 24 hours posttreatment, 6/6 rabbits had corneal opacity (6/6 = 5); 2/6 iris irritation (2/6 = 5); 6/6 conjunctive redness (2/6 = 1, 3/6 = 2, 1/6 = 3) and swelling (2/6 = 1, 4/6 = 2); suppuration, pupil contracted and small retractions in the eyelids. At 8 days, 5/6 had corneal opacity (3/6 = 5, 2/6 = 10); 1/6 iris irritation (1/6 = 5); 5/6 redness (2/6 = 1, 2/6 = 2, 1/6 = 3) and 1/6 swelling (1/6 = 1); detachment of the cornea, marginal vascularization of the cornea, pupil contracted, small retractions in the eyelids and suppuration also reported.

STUDY CLASSIFICATION:

Core Minimum Data. Observations must be made for 21 days posttreatment or until all irritation has subsided, whichever comes first.

006270

TOXICITY CATEGORY: I - DANGER.

(4) Dermal Irritation Study: BASF Aktiengesellschaft;  
Project ID IH4125/85, April 19, 1985, EPA MRID  
No. 400313-05.

PROCEDURE:

Six rabbits with intact skin sites each were treated with 0.5 ml of the test material under occlusive wrap for 4-hour exposure period. Observations made for 72 hours posttreatment.

RESULTS:

At 24 hours posttreatment, 2/6 rabbits had redness (1/6 = 1, 1/6 = 2). Redness had cleared by 72 hours.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

Acifluorfen

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Pages 5 through 6 are not included in this copy.

The material not included contains the following type of information:

- \_\_\_\_\_ Identity of product inert ingredients.
- \_\_\_\_\_ Identity of product inert impurities.
- \_\_\_\_\_ Description of the product manufacturing process.
- \_\_\_\_\_ Description of product quality control procedures.
- \_\_\_\_\_ Identity of the source of product ingredients.
- \_\_\_\_\_ Sales or other commercial/financial information.
- \_\_\_\_\_ A draft product label.
- \_\_\_\_\_ The product confidential statement of formula.
- \_\_\_\_\_ Information about a pending registration action
- \_\_\_\_\_ FIFRA registration data.
- \_\_\_\_\_ The document is a duplicate of page(s) \_\_\_\_\_
- \_\_\_\_\_ The document is not responsive to the request.

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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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